at levels not to exceed current good manufacturing practice.

[42 FR 48336, Sept. 23, 1977, as amended at 49 FR 5613, Feb. 14, 1984; 50 FR 3755, Jan. 28, 1985; 53 FR 52682, Dec. 29, 1988]

§ 184.1560 Ox bile extract.

(a) Ox bile extract (CAS Reg. No. 8008–63–7), also known as purified oxgall or sodium choleate, is a yellowish green, soft solid, with a partly sweet, partly bitter, disagreeable taste. It is the purified portion of the bile of an ox obtained by evaporating the alcohol extract of concentrated bile.

(b) Food-grade ox bile extract shall meet the specifications of the U.S. Pharmacopeia (USP), XIV, 1950, p. 410.[1]

(c) The ingredient is used as a surfactant as defined in §170.3 (o)(29) of this chapter.

(d) The ingredient is used in food in accordance with §184.1(b)(1) at levels not to exceed good manufacturing practice. Current good manufacturing practice results in a maximum level, as served, of 0.002 percent for cheese as defined in §170.3(n)(5) of this chapter.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[43 FR 36064, Aug. 15, 1978. Redesignated and amended at 50 FR 49537, Dec. 3, 1985]

§ 184.1563 Ozone.

(a) Ozone (O_3, CAS Reg. No. 10028–15–6) is an unstable blue gas with a pungent, characteristic odor, which occurs freely in nature, It is produced commercially by passing electrical discharges or ionizing radiation through air or oxygen.

(b) The ingredient must be of a purity suitable for its intended use in accordance with §170.30(h)(1) of this chapter.

(c) In accordance with §184.1(b)(2), the ingredient is used to treat food only within the following specific limitations:

Category of food	Maximum treatment level in food	Functional use
Bottled water that prior to ozonation meets the microbiological, physical, chemical, and radiological quality standards of §165.110 (b)(2) through (b)(5) of this chapter.	Not to exceed current good manufacturing practice. Current good manufacturing practice results in a maximum residual level at the time of bottling of 0.4 milligram of ozone per liter of bottled water.	Antimicrobial agent, §170.3 (o)(2) of this chapter.

[47 FR 50210, Nov. 5, 1982, as amended at 60 FR 57130, Nov. 13, 1995]

§ 184.1583 Pancreatin.

(a) Pancreatin (CAS Reg. No. 8049–47–6) is an enzyme preparation obtained from porcine or bovine pancreatic tissue. It is a white to tan powder. Its characterizing enzyme activity that of a peptide hydrolase (EC 3.4.21.36).

(b) The ingredient meets the general requirements and additional requirements in the Food Chemicals Codex, 3d ed. (1981), p. 110, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of Premarket Approval (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as GRAS as a direct food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in §170.3(o)(9) of this chapter to hydrolyze proteins or polypeptides.

[1] Copies may be obtained from: U.S. Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

[60 FR 32911, June 26, 1995]

§ 184.1585 Papain.

(a) Papain (CAS Reg. No. 9001–73–4) is a proteolytic enzyme derived from *Carica papaya* L. Crude latex containing the enzyme is collected from slashed unripe papaya. The food-grade product is obtained by repeated filtration of the crude latex or an aqueous solution of latex or by precipitation from an aqueous solution of latex. The resulting enzyme preparation may be used in a liquid or dry form.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 107–110, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than currect good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing conditions of use:

(1) The ingredient is used as an enzyme as defined in § 170.3(o)(9) of this chapter; processing aid as defined in § 170.3(o)(24) of this chapter; and texturizer as defined in § 170.3(o)(32) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 48806, Oct. 21, 1983]

§ 184.1588 Pectins.

(a) The pectins (CAS Reg. No. 9000–69–5) are a group of complex, high molecular weight polysaccharides found in plants and composed chiefly of partially methylated polygalacturonic acid units. Portions of the carboxly group occur as methyl esters, and the remaining carboxyl groups exist in the form of the free acid or as its ammonium, potassium, or sodium (CAS Reg. No. 9000–59–8) salts, and in some types as the acid amide. Thus, the pectins regulated in this section are the high-ester pectins, low-ester pectins, amidated pectins, pectinic acids, and pectinates. Pectin is produced commercially by extracting citrus peel, apple pomace, or beet pulp with hot dilute acid (pH 1.0 to 3.5, 70° to 90 °C). The extract is filtered, and pectin is then precipitated from the clear extract with ethanol or isopropanol, or as the copper or aluminum salt. The acid extract is sometimes spray- or roller-dried, or it is concentrated to be sold as liquid pectin.

(b) The ingredients meet the specifications of the Food Chemical Codex, 3d Ed. (1981), p. 215, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(c) In accordance with § 184.1(b)(1), the ingredients are used in food with no limitation other than current good manufacturing practice. The affirmation of these ingredients as generally recognized as safe (GRAS) as direct human food ingredients is based upon the following current good manufacturing practice conditions of use:

(1) The ingredients are used as emulsifiers as defined in § 170.3(o)(8) of this chapter and as stabilizers and thickeners as defined in § 170.3(o)(28) of this chapter.

(2) The ingredients are used in food at levels not to exceed current good manufacturing practice.